REMARKS

Claims 1-3, 6, 15, 22, 24-27, 33, 37-39, 42-43 and 45-56 remain pending after amendment.

Allowable Subject Matter

Applicants thank the Examiner for the indication of allowability of the subject matter of claims 3, 6, 33, 37, 43, 45, 46,47, 48, 49, 50 and 51-56. However, for the reasons indicated below, all pending claims are believed to be allowable.

Withdrawal of Rejection under 35 USC 112 (paragraph one)

Applicants acknowledge the withdrawal of the prior rejection under 35 USC 112 (paragraph one) in view of the amendment of the claims to delete reference to the term "prophylaxis".

Rejection under 35 USC 102(b)

Claims 1, 2, 22, 24-26 and 42 stand rejected under 35 USC 102(b) as being unpatentable over Day U.S. Patent No. 5,380,522. This rejection respectfully is traversed.

In support of the rejection, the Examiner states at page 2 of the Action:

> "Day discloses in column 4, lines 5-63 a method of treating or preventing irritable bowel syndrome by oral administering singly or in combination an anion-binding polymer and a hydrophilic polymer. The hydrophilic polymer as taught by the prior art can be xanthan gum. It is the position of the Examiner that when the composition is administered singly, the hydrophilic polymer would the sole therapeutic agent. Column 4, line 64 through column 5, line 7 teach that the composition when prepared is in the form of a dry powder, which can be admixed with a fluid prior to ingestion. It is also the position of the Examiner that the claimed disease states would be inherent as they are diseases that result for irritable bowel syndrome and thus be treated as a result of taking the composition."

In response, applicants note that claims 1, 2, 9 and 27-28 in an Official Action of April 25, 2001 were previously rejected under 35 USC 102(b) as being anticipated by Day WO 94/04136, which corresponds to Day U.S. Patent No. 5,380,522. ***This rejection was previously withdrawn by the Examiner.*** Applicants thus disagree with the decision of the Examiner to reinstitute the prior rejection over the Day disclosure.

Notwithstanding the above, applicants again note that the cited reference discloses the use of an anion-binding polymer with a hydrophilic polymer to treat IBS. The reference is silent with respect to the treatment of ***IBD*** as required by independent claim 22, and, on this basis, it would appear that the Examiner fails to appreciate the difference between IBS and IBD. IBS (irritable bowel syndrome) is distinguished from IBD (inflammatory bowel disease) in that there is chronic inflammation of the mucosa and sub-mucosa layers of the intestine in IBD. By contrast, IBS involves abnormally increased motility of the small and large intestines without any detectable radiological or

histological evidence of organic pathology, such as observable inflammation of layers deeper than the epithelium. Effective treatment of IBS is not necessarily an effective treatment of IBD.

While the anion-binding polymer and hydrophilic polymer can be administered separately, the reference states at column 6, lines 26-29 that:

> "It is only the combination of the anion-binding polymer and hydrophilic polymer which is effective in preventing and relieving symptoms of this disease."

The anion-binding polymer is present as a bile acid sequestrant (see column 5, lines 62-68), but there is no indication that, as a class, the hydrophilic polymer has any function other than for its hydrophilic activity. Exemplified hydrohilic polymers include xanthan gum, but the reference fails to suggest that the gum alone has any pharmacological effect on either IBD or IBS.

The reference also fails to exemplify the use of xanthan gum, and is also silent with respect to the use of HPMC. Moreover, the reference discloses only an oral method of administration, with the reference being silent with respect to coating or any other method of providing a delayed release oral formulation as required by claim 1.

Again, the reference contains no teaching or suggestion of the therapeutic use of xanthan gum or HPMC in the treatment of IBD (either by oral or rectal administration). The reference also fails to disclose or suggest the use of xanthan

gum in an amount of from about 0.4 to 2.0 wt. % in such a pharmaceutical composition suitable for rectal treatment of IBD.

In view of the above, the rejection is without basis and should be withdrawn.

Rejection under 35 USC 102(e)

Claims 27 and 38 stand rejected under 35 USC 102(e) as being unpatentable over Sachetto U.S. Patent No. 5,972,310. This rejection respectfully is traversed.

In support of the rejection, the Examiner states at page 3:

> "Sachetto discloses in example 27, column 11, a composition comprising as a therapeutic agent xanthan gum in a concentration of 0.5% by weight and a pharmaceutically acceptable carrier or vehicle i.e., H_2O."

Applicants note that the claims were previously rejected over Slagel WO96/03115, which rejection was previously withdrawn in an Official Action of January 28, 2004. The Slagel '115 publication corresponds to the instantly-cited Sachetto U.S. Patent No. 5,972,310. Applicants thus disagree with the decision of the Examiner to reinstitute the prior rejection over the Slagel disclosure.

Notwithstanding the above, applicants state as follows with respect to the cited reference.

The reference discloses compositions suitable for rectal delivery or pharmaceutically active components in the treatment of conditions such as IBD, IBS and

anorectal disorders. The reference discloses at Example 1 a foamable composition consisting of 2g (or 1.9 wt.%) of the water soluble polysaccharide xanthan gum in 98g water and 1g polysorbate 80 as the sole components. It also discloses that the water soluble polysaccharide may be HPMC, and that the foam compositions may contain up to 5 wt.% water soluble polysaccharide.

The reference, however, does not disclose that the composition of Example 1 (i.e., without an active agent) would be useful in the treatment of IBD itself but it does disclose that such ***foamable*** compositions could be used to carry an active agent for rectal administration to the rectum to treat IBD. Clearly, there is no teaching of a delayed release composition in the reference, or of a liquid enema as claimed.

The rejection is thus without basis and should be withdrawn.

Rejection of Claim 15 under 35 USC 103(a)

Claim 15 stands rejected under 35 USC 103(a) as being unpatentable over Day U.S. Patent No. 5,380,522.

In support of the rejection, the Examiner states at page 4 of the Action:

> "Day discloses in column 4, lines 5-63 a method of treating or preventing irritable bowel syndrome by oral administering singly or in combination an anion-binding polymer and a hydrophilic polymer. The hydrophilic polymer as taught by the prior art can be xanthan gum. It is the position of the Examiner that when the composition is administered singly, the hydrophilic polymer would the sole therapeutic agent. Column 4, line 64 through column 5, line 7 teach

> that the composition when prepared is in the form of a dry powder, which can be admixed with a fluid prior to ingestion. The prior art does not teach composition containing concentrations of the polysaccharide from about 400 to about 2000 mg."

Claim 15 depends from claim 1 which is shown above to patentably distinguish over the cited reference. The rejection of claim 15 is thus also without basis and should be withdrawn.

Rejection of Claim 39 under 35 USC 103(a)

Claim 39 stands rejected under 35 USC 103(a) as being unpatentable over Sachetto U.S. Patent No. 5,972,310. This rejection respectfully is traversed to the extent deemed to apply to the claims as amended.

> "Sachetto discloses in example 27, column 11, a composition comprising as a therapeutic agent xanthan gum in a concentration of 0.5% by weight and a pharmaceutically acceptable carrier or vehicle i.e., H_2O. The prior art does not teach composition containing concentrations of the polysaccharide from about 400 to about 2000 mg."

Claim 39 depends from claim 27, which claim has been shown above to patentably distinguish over the cited reference. Given the distinctions that exist between claim 27 and the reference, the instant rejection is also without basis and should be withdrawn.

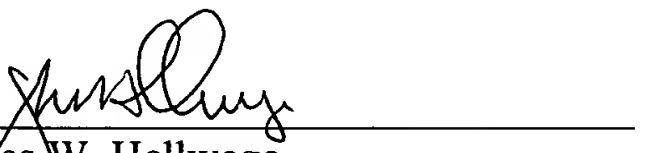
The application is now believed to be in condition for allowance and an early indication of same is earnestly solicited.

In the event that any outstanding matters remain in this application, Applicants request that the Examiner contact James W. Hellwege (Reg. No. 28,808) at (703) 205-8000 to discuss such matters.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

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